ORAL ARGUMENT NOT YET SCHEDULED

No. 24-1135
(consolidated with Nos. 24-1228, 24-1246, 24-1249, 24-1250, 24-1251, 24-1252)

In The United States Court of Appeals for the District of Columbia Circuit

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DENKA PERFORMANCE ELASTOMER LLC, *ET AL.*,
Petitioners,
v.

ENVIRONMENTAL PROTECTION AGENCY, *ET AL.*,
Respondents.

and

AIR ALLIANCE HOUSTON, *ET AL.*,
Intervenors for Respondent.

On Petition for Review of a Final Agency Action
of the Environmental Protection Agency

OPENING BRIEF OF PETITIONERS DENKA PERFORMANCE ELASTOMER LLC, THE STATE OF LOUISIANA AND THE LOUISIANA DEPARTMENT OF ENVIRONMENTAL QUALITY

Dated: January 17, 2025

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties

The following are parties in this Court:

a. Petitioners: American Chemistry Council; American Fuel & Petrochemical Manufacturers; Denka Performance Elastomer LLC; Huntsman Petrochemical LLC; State of Louisiana; Louisiana Chemical Association; Louisiana Department of Environmental Quality; State of Texas; and Vinyl Institute, Inc.

b. Respondents: Environmental Protection Agency and Michael Regan, in his official capacity as Administrator of the Environmental Protection Agency

c. Intervenors for Respondents: Air Alliance Houston; California Communities Against Toxics; Concerned Citizens of St. John; Environmental Defense Fund; Environmental Integrity Project; Louisiana Environmental Action Network; Rise St. James Louisiana; Sierra Club; and Texas Environmental Justice Advocacy Services.

B. Rulings Under Review

Petitioners seek review of EPA's *New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission*

Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry, published in the Federal Register at 89 Fed. Reg. 42,932 (May 16, 2024), JA___-___.

C. Related Cases (consolidated cases)

Counsel is aware of the following cases that raise similar challenges to EPA's regulatory authority:

1. *State of Louisiana, et al. v. EPA*, No. 24-1228;

2. *State of Texas, et al. v. EPA*, No. 24-1246;

3. *American Chemistry Council, et al. v. EPA*, No. 24-1250;

4. *Concerned Citizens of St. John, et al. v. EPA*, No. 24-1251; and

5. *Huntsman Petrochemical LLC v. EPA*, No. 24-1252.

RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Circuit Rule 26.1, Petitioners provide the following statements:

Denka Performance Elastomer, LLC (DPE or Denka) is a privately owned limited liability company formed under the laws of the State of Delaware, headquartered in LaPlace, Louisiana, and authorized to do business in the State of Louisiana. DPE owns and operates a manufacturing facility in LaPlace, Louisiana that produces Neoprene by utilizing chloroprene, a chemical regulated under the EPA final rule at issue in this appeal. DPE's membership interests are held by Denka USA LLC (whose ultimate parent is Denka Company Limited) and Diana Elastomers, Inc. (whose ultimate parent is Mitsui & Co., Ltd). Denka Company Limited and Mitsui & Co. Ltd. are each Japanese companies listed on the Tokyo Stock Exchange.

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GLOSSARY

EPA	Environmental Protection Agency
CAA	Clean Air Act
2024 Rule or the Rule	*New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry*, 89 Fed. Reg. 42,932 (May 16, 2024)
IRIS	Integrated Risk Information System
Benzene Rule	*National Emission Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants*, 54 Fed. Reg. 38,044 (Sept. 14, 1989)
IUR	Inhalation unit risk
MIR	Maximum individual risk
PBPK model	Physiologically-based pharmacokinetic model
NRC	National Research Council

INTRODUCTION

This brief addresses issues that are relevant only to Denka Performance Elastomer ("Denka") and the State of Louisiana, where Denka's facility ("Facility") is located. This brief generally uses the same defined terms as the combined brief of the industry petitioners to which Denka is a signatory ("Combined Brief").

JURISDICTIONAL STATEMENT

Incorporated from the Combined Brief.

STATEMENT OF ISSUES

1. Whether EPA unlawfully imposed requirements on chloroprene emissions from Denka's Facility by failing to follow statutory requirements for setting such standards.

2. Whether EPA's failure to respond to relevant and significant comments regarding EPA's proposed chloroprene standards was arbitrary and capricious.

3. Whether EPA's imposition of a 90-day compliance deadline on Denka's Facility, when all other similarly situated facilities were given two years to comply, was arbitrary and capricious.

4. Whether EPA's purported revocation of Louisiana's authority to issue a compliance extension to Denka was arbitrary and capricious or otherwise contrary to law.

STATUTES AND REGULATIONS

Pertinent statutes and regulations are contained in the addendum to the Combined Brief or the addendum attached hereto.

STATEMENT OF THE CASE

Incorporated from Combined Brief.

SUMMARY OF ARGUMENT

1. Congress requires EPA to consider a variety of factors in setting risk-based standards under §112(f)(2). 42 U.S.C. §7412(f)(2). Yet here, EPA set such standards for chloroprene by relying exclusively on a single "IRIS" value that was calculated in 2010.

2. Denka submitted detailed and substantive comments showing that the IRIS value greatly exaggerates the cancer risk posed by chloroprene emissions. EPA utterly failed to consider or respond to several such comments, in violation of the Administrative Procedure Act and the Clean Air Act ("CAA").

3. The Rule requires Denka to comply within 90 days but gives all other regulated sources two years to comply, despite EPA's finding that some pose a much *greater* risk to public health than Denka. This disparate treatment of Denka is arbitrary and capricious.

4. As with most states, Louisiana has authority to issue compliance extensions to facilities within its borders. The Rule purports to divest Louisiana of

authority to issue such an extension to Denka, without providing any explanation or having mentioned this issue in the proposed rule. This is arbitrary and capricious.

STANDING

Denka has "self-evident" standing because it is "directly regulated by the challenged rule." *Am. Fuel & Petrochemical Manufacturers v. EPA*, 3 F.4th 373, 379 (D.C. Cir. 2021). Louisiana and the Louisiana Department of Environmental Quality plainly have standing because they will be directly impacted by the Rule, especially considering EPA's effort to divest Louisiana of delegated authority to grant extension requests.

ARGUMENT

I. In Setting Risk-Based Standards For Chloroprene Under §112(f)(2), EPA Has Ignored Statutory Requirements For Setting Such Standards.

Based on EPA's well-established methodology for quantifying the benefits of reducing health risks, the Rule's chloroprene requirements will provide approximately $653,000 per year in health benefits.[1] Denka Comments 51-52. EPA does not dispute this value. EPA itself estimated that the annualized cost of meeting

[1] EPA claims that these requirements will prevent one cancer case every 17 years. 88 Fed. Reg. 25,109. According to EPA, the value of avoiding a premature death is $11.1 million. *See* https://www.epa.gov/sites/default/files/2017-08/documents/ee-0568-50.pdf. Assuming every cancer case that EPA attributes to chloroprene causes a premature death and that the Rule's chloroprene requirements prevent one cancer case every 17 years, the benefits of those requirements are just under $653,000 annually.

those requirements is $10.4 million per year.[2] 88 Fed. Reg. 25,122 (Table 9). Thus, using EPA's own numbers, the cost of the chloroprene requirements is almost *16 times higher* than the benefits claimed by EPA.

Instead of using its authority under §112(d)(6) to regulate chloroprene by weighing costs and benefits, EPA used its "discretion" to set a second round of "residual risk" standards under §112(f)(2), which allows EPA to ignore certain costs when doing so. But even if EPA has discretion to set a second round of residual risk standards, it has done so here based *entirely* on a single numerical estimate of risk known as an "inhalation unit risk" ("IUR") value and has ignored all other factors that Congress requires EPA to consider when setting such standards. EPA also failed to respond to significant comments showing that EPA has substantially overstated the risk of chloroprene.

A. EPA Must Weigh A Variety Of Factors In Setting Residual Risk Standards Under §112(f)(2)—Not Just A Single Quantified Risk Estimate.

As discussed on pages 10-11 of the Combined Brief, Congress mandated that EPA use a particular approach laid in the 1989 Benzene Rule for setting residual risk standards under §112(f)(2). 42 U.S.C. §7412(f)(2)(B); *see* 54 Fed. Reg. 38,044

[2] Denka submitted detailed estimates from outside engineering firms showing that the actual annualized cost of meeting those requirements (not including the cost of meeting EPA's "action levels" for chloroprene) would be about $26 million. Denka Comments 74-92.

(Sept. 14, 1989). In the Benzene Rule, EPA considered four approaches for determining whether risk was "acceptable" or whether additional emission standards are necessary to reduce risk. 54 Fed. Reg. 38,045. Under one approach, EPA would consider "only a single health measure"—the "maximum individual risk" of cancer, meaning the risk to a hypothetical person "exposed to the maximum pollutant concentration for 70 years." *Id.* If that risk were higher than 1-in-10,000 (0.01%), it would automatically be deemed unacceptable. *Id.* EPA expressly *rejected* this approach in the Benzene Rule—but, as discussed below, *this is precisely the approach that EPA has taken here with chloroprene.*

The approach laid in the Benzene Rule (since codified by Congress) is as follows: EPA starts with a presumption that a risk of 1-in-10,000 is roughly the level of acceptability but must then consider a number of other factors to make "an overall judgment on acceptability." *Id.* As EPA explained, "[i]n establishing a presumption for [maximum individual risk of 1-in-10,000], rather than a rigid line for acceptability, the Agency intends to weigh it with a series of other health measures and factors," including "the science policy assumptions and estimation uncertainties associated with the risk measures, [and the] *weight of the scientific evidence for human health effects.*" *Id.* 38,046 (emphasis added). EPA also noted that "numerical risk . . . based on limited animal test data . . . cannot be given the same weight" as evidence in humans. *Id.*

The specific details EPA must consider when setting residual risk standards are fact specific. But Congress, by codifying the Benzene Rule, made clear that EPA must make an "acceptability judgment" that goes beyond a numerical estimate of cancer risk based on animal data. As EPA noted, "judgment must be used in deciding how numerical risk estimates are considered" and "uncertainties arising from such factors as the lack of knowledge about the biology of cancer causation and gaps in data must be weighed. . . ." 54 Fed. Reg. 38,045.

B. The Benzene Rule Requires EPA To Maintain The Distinction Between "Risk Assessment" And "Risk Management."

The Benzene Rule approach was designed to conform to the risk framework established by the National Research Council ("NRC") in 1983. *See* 54 Fed. Reg. 38,062-63; NRC, *Risk Assessment in the Federal Government*. At the highest-level, that framework is divided between "risk assessment" and "risk management." *Id.* 3. As EPA has noted, "risk assessment and risk management are 'two distinct elements' between which agencies should maintain a clear conceptual distinction." EPA, *The NRC Risk Assessment Paradigm* (updated 9/13/24), https://www.epa.gov/fera/nrc-risk-assessment-paradigm). As EPA summarized this distinction:

> Risk assessment establishes whether a risk is present and, if so, the range or magnitude of that risk. In the risk management process, the results of the risk assessment are integrated with other considerations.

EPA, Risk Management, https://www.epa.gov/risk/risk-management (last visited 1/10/25). Setting residual risk standards is a risk management decision, and the "other considerations" that EPA must consider are enumerated in the Benzene Rule.

Although risk assessment and risk management are distinct, risk management decisions must consider multiple aspects of the underlying risk assessment. Under the Benzene Rule, these include "the science policy assumptions and estimation uncertainties associated with the risk measures" and the "weight of the scientific evidence for human health effects." 54 Fed. Reg. 38,045. Moreover, "judgment must be used in deciding how numerical risk estimates are considered." *Id.* Here, however, EPA refused to consider any of these factors. EPA made risk management decisions for chloroprene (the residual risk standards) based entirely on one numerical risk estimate (the IUR) derived from effects seen in female mice—without considering underlying assumptions and uncertainties and substantial body of evidence suggesting that this numerical value substantially overstates cancer risk in humans.

C. The Role Of The IRIS Program In Risk Assessment.

EPA has created the Integrated Risk Information System or "IRIS" program specifically to conduct risk assessments. The IRIS program publishes "toxicological reviews" for individual chemicals that provide information about these assessments. *See* EPA, Basic Information about IRIS (last updated 10/21/24),

https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.

For many chemicals, one part of the toxicological review is developing an "IUR" value, which estimates a person's chances of getting cancer as a result of 70 years of continuous exposure to a pollutant for each "microgram per cubic meter" ($\mu g/m^3$) of that pollutant in the ambient air. Thus, an IUR of 0.1 for a pollutant means that a person inhaling an average concentration of 1 $\mu g/m^3$ of that pollutant for 70 years would have an estimated 0.1 (or 1-in-10) chance of developing cancer as a result. But EPA cautions that this single IUR-value must be interpreted in light of numerous uncertainties and qualitative assumptions involved in calculating this number. *See, e.g.,* 2010 Toxicologic Review of Chloroprene ("2010 IRIS Review") 138-142 (discussing seven sources of uncertainty in chloroprene IUR).

The NRC also cautions that officials making risk management decisions must consider the importance of assumptions and uncertainties in any risk assessment:

> Conclusions based on a large number of sequential, discretionary choices necessarily entail a large, cumulative uncertainty. The degree of uncertainty may be masked to some extent when, in the final form of an assessment, risk is presented as a number with an associated measure of statistical significance. If they are to be most instructive to decision-makers, assessments should provide some insight into qualitative characteristics of the data and interpretations that may impute more or less certainty to the final results.

NRC, *Risk Assessment in the Federal Government* 165.

Consistent with these cautions, EPA guidance issued shortly after §112(f)(2) was adopted states that IRIS values are "only a starting point for risk assessment" and "not meant to replace careful thought and analysis necessary" for making regulatory decisions. *Guidance on Use of Integrated Risk Information System (IRIS) Values* (Aug. 26, 1994). This guidance warns that EPA "should not rely exclusively on IRIS values but should consider all credible and relevant information that is submitted in any particular rulemaking." *Id.* 2. This is consistent with the Benzene Rule:

> [EPA] recognizes that consideration of maximum individual risk ("MIR")—the estimated risk of contracting cancer following a lifetime exposure at the maximum, modeled long-term ambient concentration of a pollutant—must take into account the strengths and weaknesses of this measure of risk.

54 Fed. Reg. 38,045.

D. The Chloroprene IUR And Denka's Requests For Correction Under EPA's Scientific Integrity Guidelines.

In the 2010 IRIS Review for chloroprene, EPA reviewed studies exposing four different types of laboratory animals to chloroprene. For comparable numbers of animals, the number of observed lung tumors were as follows:

Hamsters	**0**
Wistar rats	**0**
Fischer rats	**18**
Mice	**118**

Denka comments 25. The results also showed that cancer incidence in *female* mice was almost twice as high as in *male* mice. The range of effects in animals is a result

of biological or "pharmacokinetic" differences in species and, as EPA's outside peer reviewers noted, this particular species of mouse is known to be particularly susceptible to lung tumors because of its high metabolic rate. *See* EPA*, Final Reviewer Comments: External Peer Review Meeting on the Toxicological Review of Chloroprene*, 30-31, 62 (1/26/10).

However, in calculating the chloroprene IUR, EPA relied *entirely* on the results in female mice, even though four of EPA's six peer reviewers raised concerns that this would overestimate chloroprene's cancer risk to humans, and two reviewers recommended that EPA use the results in Fischer rats instead. *Id*. In responding to concerns that Denka raised about this issue, EPA simply stated:

> In accordance with the EPA Guidelines for Carcinogen Risk Assessment (2005), in the absence of data to the contrary, EPA utilizes the most sensitive species and sex in estimating cancer risk to humans, which in the case of chloroprene, is the female mouse.

EPA's Denial of Request for Correction #170023.

However, EPA did acknowledge that "[a] number of uncertainties underlie the cancer unit risk for chloroprene," especially "uncertainty from the interspecies extrapolation of risk from mouse to human." 2010 IRIS Review 138, 141. EPA stated that it would prefer to have a physiologically-based pharmacokinetic ("PBPK") model to determine the IUR for humans by accounting for the key biological and pharmacokinetic differences between female mice and humans. *Id.* A PBPK model is a computer model that describes how humans or animals process

chemicals by accounting for species-specific parameters and simulating the uptake, distribution, metabolism, and elimination of a chemical.[3]

The chloroprene IUR received little attention until December 2015, when EPA released its "2011 National Air Toxics Assessment." Based on the chloroprene IUR, EPA's assessment alleged that cancer risk to the community around the Facility was higher than around any other industrial facility in the Nation. *See* https://www.epa.gov/sites/default/files/2015-12/2011nata_national_cancerrisk_by_tract_poll.xlsx (listing top 5 census tracts for cancer risk).

Because of understandable concerns arising from this assessment, Denka promptly installed $35 million in pollution control equipment and reduced emissions by more than 85%. Because Denka strongly disputed EPA's claims about chloroprene's cancer risk in humans, Denka also submitted, in June 2017, a "Request for Correction" under EPA's *Scientific Integrity Guidelines*, which provide a process for requesting that EPA correct its scientific assessments.

Denka noted that, when EPA calculated the chloroprene IUR, it disregarded key comments from its own peer reviewers and, in one case, improperly performed a follow-up analysis recommended by peer reviewers. EPA denied Denka's Request

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[3] *See* https://www.epa.gov/sites/default/files/2018-02/documents/pbpk_factsheet_feb2018_0.pdf.

for Correction in January 2018, on the grounds that Denka failed to provide new scientific information that was not considered in the 2010 IRIS Assessment. Denka Comments, Attachment 3 at 14 (1/25/18 EPA letter).

Because of EPA's recognition that a PBPK model would allow EPA to calculate an IUR for humans by accounting for the key biological and pharmacokinetic differences between female mice and humans, Denka then spent several years (and considerable resources) working with EPA and experts at Ramboll US Consulting, Inc. ("Ramboll") to develop a robust PBPK model for chloroprene. *See* Denka Comments 13 (describing Denka/Ramboll/EPA interactions in developing PBPK model). In April 2018, Ramboll submitted a proposed work plan to EPA and then developed and submitted a proposed PBPK model to EPA. At EPA's request, Ramboll then conducted a costly experiment to provide data relating to one key aspect of the model. The 2019 version of the PBPK model was then peer reviewed and published in *Inhalation Toxicology*.[4]

EPA then retained a contractor to oversee an external peer review of the Ramboll model. The peer reviewers provided comments that Ramboll fully addressed over the following months and incorporated into its 2021 PBPK model.

[4]*Incorporation of in vitro metabolism data and physiologically based pharmacokinetic modeling in a risk assessment for chloroprene*. Inhalation Toxicology, 31(13-14): 468-483.

In July 2021, Denka presented this model to EPA in a second Request for Correction, asking EPA to revise the chloroprene IUR based on it. *See* Attachment 3 to Denka Comments.

In December 2021, EPA convened a "Follow-up External Peer Review" of the updated model, and three of the four peer reviewers who commented on the 2021 PBPK model endorsed its use, saying it was a "reliable tool" and "scientifically sound." 2021 Follow-Up Peer Review 21, 27; Denka Comments 45. The other reviewer acknowledged the Ramboll experts as "highly respected scientists" but said that "we must be very, very careful" when using a PBPK model "to justify the relaxation of risk assessment." *Id.* at 56. He did not provide a scientific basis for this concern.[5]

To Denka's surprise, EPA denied Denka's second Request for Correction in March 2022. Notably, EPA did *not* base its denial on any concerns about the 2021 PBPK model. Rather, EPA said it was not legally obligated to update the 2010 IRIS Review and, because chloroprene was not an EPA priority, it declined to devote its limited resources to doing so. *See* Attachment 3 to Denka Comments 2-3 (3/22/22 EPA letter).

[5] Two other peer reviewers without expertise in PBPK modeling provided no comments on the updated model.

EPA did, however, provide Denka with a superficial "courtesy review" of the 2021 PBPK model, concluding that the PBPK model was inconsequential because it would only change the estimate of chloroprene's cancer risk by a factor of two, and "[t]his factor of 2 difference is well within the generally accepted uncertainty for cancer risk estimation." *Id.*, Exhibit 1A.

E. EPA Issued Proposed And Final Residual Risk Standards Relying Entirely On The Chloroprene IUR.

On April 23, 2023, EPA issued its Proposed Rule that included extraordinarily costly residual risk standards for chloroprene under §112(f)(2). These standards were based entirely on the chloroprene IUR. Remarkably, the proposal did not mention the PBPK model.

Denka submitted extensive comments on the proposed rule—including multiple expert declarations. A declaration from an acknowledged PBPK expert explained why EPA's "courtesy review" of the 2021 PBPK model was incorrect. Gentry Decl. ¶ 65. She explained, based on a peer reviewed study, that the model would not just change the IUR by a factor of two, as EPA claimed, *but by a factor of 35. Id.* ¶ 71.

Denka also submitted two major post-2010 studies that evaluated the cancer risk of chloroprene in humans, supported by expert declarations. The first was an update from the Louisiana Tumor Registry, a program funded by Louisiana that tracks all cancer cases in the State. It found that cancer rates for the predominant

cancers of concern for chloroprene in the Parish where the Denka Facility is located are below state-wide averages and that cancer incidence for all cancers in the Parish is in the bottom 25% of the state.

The second study updated a long-term epidemiological study of workers exposed to chloroprene that was published in a peer reviewed journal in March 2021. It showed that, even among workers exposed to high levels of chloroprene for decades, there was no evidence of increased cancer mortality.

These materials submitted by Denka are discussed in more detail in Part II below, which discusses EPA's responses. In the final Rule, EPA inexplicably set residual risk standards based entirely on the chloroprene IUR. EPA placed no weight on the above studies or on anything but the IUR, and it failed to meaningfully respond, or even respond at all, to relevant and significant comments.

II. EPA Failed To Consider Or Provide Relevant Responses To Denka's Principal Comments.

Denka submitted substantial comments on the factors that EPA is required to consider under the Benzene Rule when making risk management decisions—*i.e.*, setting residual risk standards—under §112(f). EPA failed even to respond to some of them, and when EPA did respond, its responses routinely referenced or repeated statements from the 2010 IRIS Review or from EPA's denials of the two "Requests for Correction" that Denka submitted under EPA's *Scientific Integrity Guidelines*. Those guidelines establish a process by which outside parties may request that EPA

correct or update *scientific assessments* (although to our knowledge, EPA has never actually granted such a request). But that process deals only with *risk assessment*, which is separate and apart from the *risk management* decisions that EPA must make under §112(f)(2) in accordance with the framework established in the Benzene Rule.

Denka is not asking this Court to overrule the chloroprene IUR. Rather, Denka is challenging the residual risk standards for chloroprene based on EPA's utter failure to consider other factors besides the IUR that, as a matter of law, EPA must consider when setting standards under §112(f)(2). The IRIS program is not responsible for making risk management decisions or considering all the factors that EPA is required to consider in setting such standards. And many of the IRIS program responses that EPA repeats in responding to Denka's comments are simply not relevant here.

A. EPA Entirely Failed To Respond To Comments Showing That The Assertions In EPA's "Courtesy Review" Of The 2021 PBPK Model Were Simply Wrong.

When EPA denied Denka's request that EPA use the 2021 PBPK model to reconsider the chloroprene IUR, EPA did not say it was not fit for this purpose. *See supra* 13. Rather, EPA simply declined to reconsider the IUR and stated: "[E]ven if the current Ramboll PBPK model were accepted at face value and applied…, the total estimated cancer risk would be reduced by no more than 50%" because "the lung only accounts for about 40% of the total cancer incidence in mice," and the

PBPK model could not be used to assess risk in other tissues. EPA Response to Comments 107. "This factor of 2 difference," EPA said, "is well within the generally accepted uncertainty for cancer risk estimation," and the IUR "did not over-estimate the human cancer risk by multiple orders of magnitude, as contended by Denka and Ramboll." *Id*.

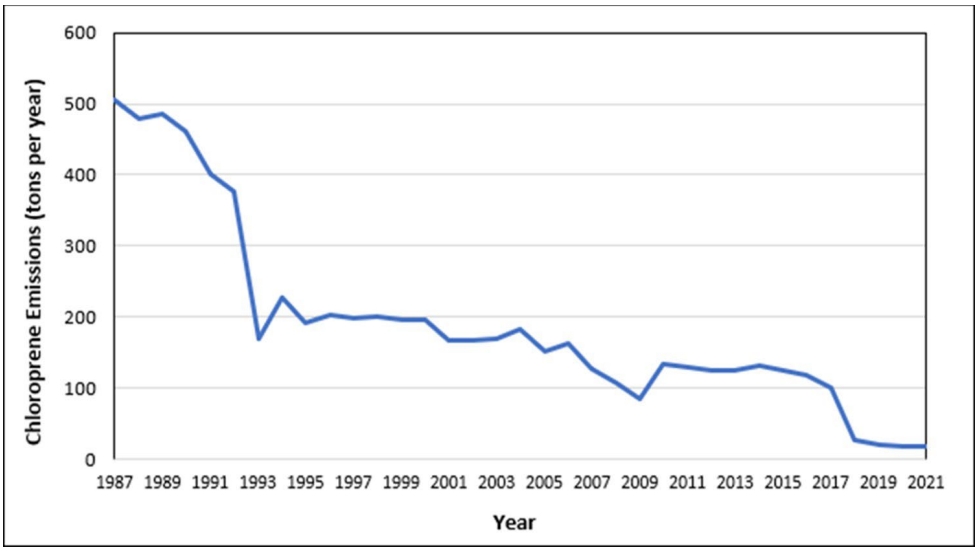
In its comments, Denka provided a declaration from Dr. Robinan Gentry of Ramboll, an acknowledged PBPK expert, who explained why this conclusion was simply wrong—that the PBPK model does indeed account for cancer in non-lung tissues. Gentry Declaration 24-25. Specifically, Dr. Gentry relied on a published, peer-reviewed analysis to show that the Ramboll PBPK model specifically accounts for lung and liver tumors (85% of all tumors observed in the data) and that there was no evidence of a dose-response relationship with chloroprene for the remaining tumor types. *Id.* Dr. Gentry explained that the position EPA took in the courtesy review was based on the flawed assumption that tumor types formed independently, resulting in "double counting" of tumors." *Id.* In its 2010 IRIS review, EPA actually acknowledged this possibility: "It was assumed that the tumor types . . . were statistically independent" but "[t]his assumption cannot currently be verified and if not correct could lead to an overestimate of risk from summing across tumor sites." 2010 IRIS Review 136. Dr. Gentry provided a peer reviewed study showing that this assumption was incorrect. Gentry Decl. ¶ 67 (referencing Sax *et. al.* "Extended

Analysis and Evidence Integration of Chloroprene as a Human Carcinogen," *Risk Analysis* 40(2):294-318 (2020)).

In response, EPA simply said that it disagreed. It made no effort to explain why Dr. Gentry's explanation—or the study it relies upon—was wrong. This is not a trivial issue—it is the difference *between a reduction by a factor of two and a reduction by a factor of 35* in the estimate of the cancer risk from chloroprene. This failure alone renders the Rule's residual risk requirements for chloroprene arbitrary and capricious. *See Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1312 (D.C. Cir. 2014) ("The arbitrary and capricious standard . . . includes a requirement that the agency…respond to 'relevant' and 'significant' public comments" and "an agency's failure to respond to relevant and significant public comments generally demonstrates that the agency's decision was not based on a consideration of relevant factors.") (internal cites and quotes omitted).

B. EPA's Response To The Updated Data From The Louisiana Tumor Registry Misses The Mark.

As Denka explained in its comments, Denka acquired the Facility from DuPont in 2015, but the Facility was built in the late 1960s and has been operating since that time. Denka's comments included the following graph based on EPA data. It shows the decline in the Facility's chloroprene emissions from 1987 to 2021:



As shown, the Facility emitted approximately 500 hundred tons of chloroprene in 1987—and presumably similar levels for more than 20 years before that time. By the time EPA issued the Rule, the Facility's chloroprene emissions had dropped by 96% and more than 85% just since 2016.

Denka's comments included a report from the Louisiana Tumor Registry, described above, showing that a recent update to the Registry "found not only that cancer rates for lung and liver (the predominant cancers of concern for chloroprene) are below state-wide averages in St. John the Baptist Parish, where the Denka Facility is located, but that St. John the Baptist parish is in the bottom 25% of the state for cancer incidence for all cancers combined." Denka Comments 36; *see also* LSU Health, Louisiana Cancer Data Visualization, https://sph.lsuhsc.edu/louisiana-tumor-registry/datausestatistics/louisiana-data-interactive-statistics/louisiana-cancer-data-visualization/. Notably, even after many decades with much higher

chloroprene emission rates, there is no increase in cancer rates near the Facility. *See* Denka Comments 14; *see also* Declaration of Dr. Gary Marsh 37-57 (discussing Registry data and historical chloroprene exposures).

EPA's response to this information is puzzling: "While those registries track the types of cancers, they cannot identify a particular facility or chemical as the cause of someone's cancer. Cancer is a complex disease with many causes, and determining the exact cause of any one cancer case is not something the EPA is able to do." EPA Response to Comments 121. But Denka was not seeking to attribute any cancer case to any cause. The Registry data is significant because it demonstrates that increased rates of cancer do not exist in the area surrounding the Facility, even after decades when the Facility was emitting chloroprene at levels many times higher than today.

C. EPA Failed To Respond To An Updated Epidemiological Study And Other Epidemiological Information Provided In Denka's Comments.

Denka submitted a peer-reviewed study published In the *Journal of Occupational and Environmental Medicine* in 2021 that provided an update to an epidemiological study of a historical cohort of workers exposed to chloroprene at very high levels over many decades. Denka also provided a declaration by the study's author, Dr. Gary Marsh from the University of Pittsburgh. He noted that one cohort of workers in the study had been exposed to chloroprene at concentrations

more than 450 times higher than chloroprene exposure estimates for residents living closest to Denka's Facility, but his study showed no increase in cancer mortality in workers exposed to chloroprene at any level. He concluded, based on extensive data and analysis discussed in his study and declaration, that the best available epidemiological data show *no* association between exposure to chloroprene in the workplace and mortality from lung or liver cancer—the cancers on which the chloroprene IUR is based.

In responding to comments, EPA listed the expert opinions provided by Dr. Marsh, *see* EPA Response to Comments 112, but EPA made no effort to engage or respond to them. Rather, EPA simply stated that it "does not agree with the alternative interpretation of this evidence put forward by Marsh in his declaration." *Id.* EPA also claimed that "Marsh does not cite any studies not already evaluated by EPA." *Id*. But this is hardly a sufficient response. Not only did Dr. Marsh provide a substantial amount of *new* data in 2021, but he strongly critiqued EPA's interpretation of studies cited in the prior IRIS correction request documents. But EPA simply referred back to prior IRIS documents that did not address almost 15 years of additional data or the points made in Dr. Marsh's declaration. And in any case, EPA staffers in the IRIS program were explaining why they did not revise the IUR based on the Marsh study—not why EPA chose to ignore the study when

considering the risk management factors that EPA was required to consider in this Rule.

III. EPA Set Residual Risk Standards For Chloroprene Based Entirely On One Measure Of Risk—The 2010 IUR—And Ignored Other Factors That EPA Is Required To Consider Under The Congressionally-Codified Benzene Rule.

As discussed above, *see supra* 4-5, the Benzene Rule considered and rejected the very approach that EPA has applied in setting residual risk standards for chloroprene. *See* 54 Fed. Reg. 38,045. EPA considered "only a single health measure"—the chloroprene IUR. Using this measure, EPA calculated the "maximum individual risk" of cancer, meaning the risk to a person if "he or she were exposed to the maximum pollutant concentration for 70 years." *Id.* Solely because this lifetime risk was higher than 1-in-10,000 (or 0.01%), EPA deemed it unacceptable and imposed a suite of enormously costly regulatory requirements to reduce the cancer risk below this level. This is *precisely* what EPA and Congress rejected in the Benzene Rule.

Under the Benzene Rule, EPA must make a distinction between risk assessment (the IUR) and risk management, which requires EPA to make an "overall judgement on acceptability" based on a variety of factors, including uncertainty and "science policy assumptions." 54 Fed. Reg. 38,045. The chloroprene IUR is based on a science policy assumption that is *extraordinarily* conservative here. According

to EPA science policy, when reviewing animal studies, risk assessors should seek to:

> identify the animal model that is *most relevant to humans*, based on comparability of biological effects using the most defensible biological rationale; for instance, by using comparative metabolic, pharmacokinetic, and pharmacodynamic data. *In the absence of a clearly most relevant species, however, the most sensitive species is used as a matter of science policy at the EPA*.

EPA, *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (Oct. 1994) 1-5 (emphasis added). Here, again, are the numbers of observed lung tumors in laboratory animals exposed to comparable levels of chloroprene:

Hamsters	**0**
Wistar rats	**0**
Fischer rats	**18**
Mice	**118**

Denka comments 25. Denka believes, as did at least two of the 2010 peer reviewers, that the Wistar rat should be considered the "most relevant to humans." *Id.*; EPA, *Final Reviewer Comments* 30-31 (because "metabolism rates in the rat appear similar to the human, the rat may offer a better species for prediction of human health risks"). But EPA did not believe that the Wistar rat was "clearly the most relevant species," so it used the most sensitive species "as a matter of science policy"—even though this particular species of mouse is known to be highly susceptible to lung cancers and "comparative metabolic pharmacokinetic, and pharmacodynamic data"

show that it is not a good surrogate for humans. *Id.* 62. ("One might convincingly argue that the enormous metabolic activation rate in the mouse coupled with the low epoxide hydrolysis rate renders this species inappropriate relative to the extrapolation of lung tumors). Even if EPA's choice to rely entirely on the female mouse is consistent with EPA's science policies, when EPA is setting residual risk standards under §112(f)(2), it cannot simply ignore the fact that this "science policy" almost certainly overstates the risk of chloroprene to humans.

When EPA is setting residual risk standards, the Benzene Rule also requires EPA to consider the "weight of the scientific evidence for human health effects." 54 Fed. Reg. 38,045. Here, EPA gave 100% weight to a study showing a very high cancer incidence in a particular type of female mouse known to be particularly susceptible to lung cancer. It gave zero weight to:

- A PBPK model developed over several years in consultation with EPA, which (1) has been subject to two peer reviews conducted by EPA and (2) was endorsed for use by all but one of the last group of peer reviewers who evaluated it. As discussed above, a PBPK modeling expert explained that use of this model would reduce the cancer risk estimate for chloroprene by a factor of 35, and EPA made no attempt to explain why it disagreed.

- Years of data from the Louisiana Tumor Registry showing that, even after decades when chloroprene emissions were as much as 25 times higher than current emissions, there is (1) no increase in lung or liver cancer rates near the Facility and (2) overall incidence of all cancers is well below the state average.

- A long-term, peer reviewed study of workers exposed for decades to concentrations of chloroprene many times higher than the concentrations present at the Facility's fenceline, which showed *no* increase mortality from the cancers that EPA attributes to chloroprene exposure.

- Studies showing *no* cancer risk in Hamsters or Fischer Rats, and *very low* incidence of cancer in Wistar Rats.

This, certainly, is not the "weigh[ing] of the scientific evidence for human health effects" that Congress intended when it codified the Benzene Rule.

* * * * *

This Court recently held that an agency cannot impose regulatory requirements that are more "precautionary" than Congress intended. *Nat'l Marine Fisheries Serv.,* 70 F.4th 582, 599 (D.C. Cir. 2023). When Congress codified the Benzene Rule, it told EPA just how "precautionary" it should be. According to the CDC, the average American has a 40.5% chance of getting cancer in his or her lifetime. *See* https://www.cancer.gov/about-cancer/understanding/statistics#:~:text=Approximately%2040.5%25%20of%20me. Congress mandated that EPA should start with a presumption that a pollutant should not increase this risk by more than about 0.01% (1-in 10,000), but then temper this very precautionary standard by considering a number of other factors and make an "overall judgement on acceptability" after considering "the weight of the scientific evidence for human health effects."

Here, EPA has simply ignored the second part of this mandate. EPA's chloroprene standards are contrary to law, as well as being arbitrary and capricious, and this Court should vacate them.

IV. The 90-day Compliance Deadline That Applies *Only* To *Denka* Is Arbitrary And Capricious.

The Rule requires Denka to plan for, purchase, and install millions of dollars of pollution control equipment *in only 90 days*—which EPA acknowledges is impossible—or shut down until it does.[6] This impossible-to-meet deadline is purportedly based on the cancer risk posed by Denka, but the Rule gives all other regulated sources two years to comply despite EPA's finding that some pose a *much greater cancer risk than Denka.* In more than 30 years of issuing emission standards under §112, EPA has never before imposed such a deadline—even though, according to EPA's own risk assessments, many other facilities subject to such standards have posed greater cancer risks than Denka.

"Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with *a reasoned explanation and substantial evidence* in the record, its action is arbitrary and capricious and cannot be upheld." *Burlington N. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005) (citation omitted) (emphasis added). Here, EPA provided neither a reasoned explanation nor *any* evidence in the record to support EPA's disparate treatment of Denka.

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[6] On June 27, 2024, Louisiana issued a 21-month extension of the 90-day deadline. After EPA determined that the extension was invalid, Denka challenged that determination in the Fifth Circuit and sought a stay pending review. The Fifth Circuit granted the stay, and the parties are now briefing the merits. Louisiana intervened in support to Denka.

A. Background.

The Rule sets "residual risk" standards under §112(f)(2) for at least 18 facilities that emit either ethylene oxide or chloroprene. The statute requires EPA to give sources at least 90 days to comply with such standards and provides that EPA may give sources up to two years to comply (referred to as a "waiver") if "the Administrator finds that such period is necessary for the installation of controls and that steps will be taken during the period of the waiver to assure that the health of persons will be protected from imminent endangerment." 42 U.S.C. §7412(f)(4)(A)&(B).

EPA has set residual risk standards for many source categories since §112 was adopted in 1990, and it has *always* provided sources sufficient time—commonly two years—to install the pollution controls required to comply. *See, e.g.*, 89 Fed. Reg. 24,090, 24,102 (April 5, 2024); 77 Fed. Reg. 58,220, 58,230 (Sep. 19, 2012); 77 Fed. Reg. 556, 561 (Jan. 5, 2012); 71 Fed. Reg. 42,724, 42,729-30 (Jul. 27, 2006). The allowance of sufficient time is not surprising because, as here, such standards are usually designed to protect the public from upper-bound cancer risks above 1-in-10,000 (0.01%) based on 70 years of continuous exposure. EPA has never before claimed that such risks represent an "imminent endangerment."

In the Proposed Rule, EPA gave all regulated sources two years to comply. For Denka, EPA explicitly stated that "the proposed [emission standards] will

require additional time to plan, purchase, and install equipment for … chloroprene control." 88 Fed. Reg. 25,178. In the final Rule, however, EPA imposed a 90-day deadline on Denka and no one else. The *only* thing in the rulemaking record to explain or support the switch in EPA's position and the disparate treatment of Denka is just one sentence in the Rule:

> In a change from the proposed rule, the EPA is shortening the compliance deadline for affected sources producing neoprene, due to the EPA's finding that chloroprene emissions from the only such source pose an imminent and substantial endangerment under CAA section 303, 42 U.S.C. §7603. *United States v. Denka Performance Elastomer, LLC, et al.*, No. 2:23-cv-00735 (E.D. La. filed Feb. 28, 2023).[7]

Rule 42,955. Here, EPA cites to an enforcement lawsuit (discussed below) that it brought against Denka in February 2023, months before it issued the *proposed rule*. But, even today, there has been no such "finding" in that case—merely an EPA allegation that has not been adjudicated. Further, the rulemaking record contains no analysis or evidence supporting EPA's purported "finding" of "imminent and substantial endangerment."

[7] Nothing in the proposed rule even hinted that this might be a possibility necessitating comment. This was a quintessential "surprise switcheroo" that makes the 90-day deadline procedurally arbitrary and capricious. *Env't Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005).

B. EPA's Lawsuit Under §303 Of The CAA.

In response to pressure from environmental justice advocates interacting with EPA Administrator Michael Regan,[8] EPA filed a lawsuit against Denka under §303 of the CAA in February 2023. Section 303 allows EPA to seek immediate injunctive relief in federal district court to abate an "imminent and substantial endangerment." 42 U.S.C. §7603. EPA claimed that the Facility was causing such an endangerment because, if a person were to be exposed to chloroprene emissions at the fenceline of the Facility continuously for 70 years, that person's risk of getting cancer in his or her lifetime would be increased by more than 1-in-10,000 (or 0.01%). This claim was unprecedented. EPA had never before claimed, in any type of action, that a small increase in cancer risk based on a lifetime of exposure posed an "imminent and substantial endangerment."

Two months *after* filing its §303 lawsuit, EPA issued its proposed rule that, among other things, addressed the exact same alleged risk from the Facility's chloroprene emissions. The proposed rule gave all regulated facilities, including

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[8] In November 2021, Administrator Regan met with local environmental justice activists who had filed lawsuits against Denka, and he "pledged to the community that EPA would take strong action to protect the health and safety of families from harmful chloroprene pollution from the Denka facility." EPA News Release, (Feb 28, 2023), https://epa.gov/newsreleases/epa-and-justice-department-file-complaint-alleging-public-health-endangerment-caused. He later invited the same activists to Washington D.C. for the announcement of the Rule. *See* EPA Remarks (Apr. 9, 2024), https://www.epa.gov/speeches/remarks-synthetic-organic-chemical-plants-and-polymers-and-resins-plants-final-rule-event.

Denka, two years to comply. As noted above, EPA was required to determine that, during that period, the public would be protected from "imminent endangerment."

In December 2023, Denka moved for summary judgment in the §303 case, arguing that, because the Facility's emissions do not present an "imminent endangerment," as EPA conceded by providing the two-year compliance period in the proposed rule, then there was no "imminent *and substantial* endangerment" as a matter of law. *U.S. v. DPE,* No. 2:23-cv-00735 (E.D. La.), R. Doc. 131-2 at 5-8. EPA had no meaningful response to that argument, except to say that the proposed rule was not final. *Id.* R. Doc. 150 at 5-6 & n.6.

In February 2024, after having demanded expedited litigation on the alleged "emergency" for nearly a year, EPA abruptly moved for an indefinite continuance of the trial scheduled for March. As its sole justification for postponing the trial, EPA pointed to the expected issuance of the Rule on March 29, 2024. On February 16, 2024, the district court granted EPA's continuance, and the court recently rescheduled the trial for April 14, 2025.

C. Singling Out Denka With A 90-Day Compliance Deadline Is Arbitrary And Capricious.

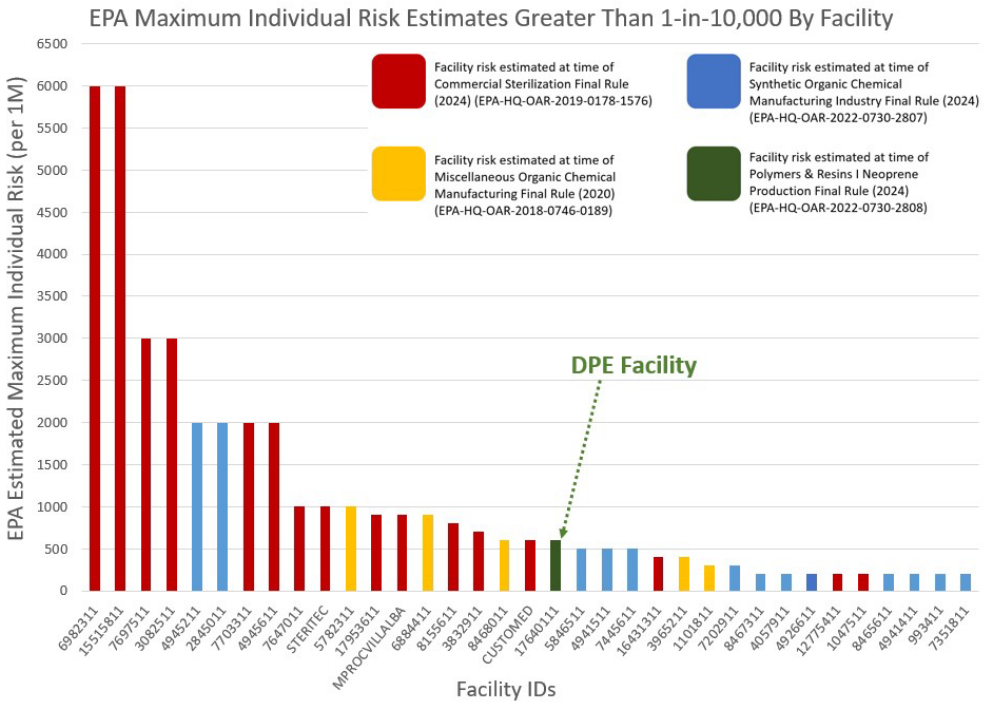
It is a bedrock principle of administrative law that agencies cannot treat similarly situated parties differently unless they provide a cogent justification for doing so. *Steger v. Def. Investigative Serv. Dep't of Def.*, 717 F.2d 1402, 1406 (D.C. Cir. 1983). "A fundamental norm of administrative procedure requires an

agency to treat like cases alike." *Westar Energy, Inc., v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007). Where an agency "applies different standards to similarly situated entities and fails to support [its] disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld." *Burlington N.*, 403 F.3d at 777. Failure to provide the "*how*" and "*why*" necessary to justify disparate treatment is arbitrary and capricious. *Lilliputian,* 741 F.3d at 1313-14.

The sole purpose of the Rule's residual risk standards is to reduce the lifetime cancer risk posed by emissions of ethylene oxide and chloroprene. This is also the sole purpose of several other residual risk rules that EPA has issued since 2020. All these rules were issued under the same statutory authority and, in each of them, EPA gave all regulated facilities—*with the sole exception of Denka*—two years to comply. EPA has singled out Denka for a 90-day deadline despite the fact that, based on EPA's own analysis, many other facilities covered by these rules pose far greater cancer risks than Denka.

In fact, EPA found that two other facilities covered by the very same Rule pose a cancer risk that is more than three times higher than the risk posed by Denka. Yet EPA gave those facilities two years to comply. JA__[89_Fed._Reg._at_43,154]. In last year's rule for commercial sterilization facilities and a 2020 rule for another chemical manufacturing source category, EPA gave all regulated facilities two-year

compliance periods, including twelve facilities with cancer risks higher than Denka's. JA__[89_Fed._Reg._24,090,_24,102;_EPA_Docket_No._EPA-HQ-OAR-2018-0746-0189_at_Table 2a-1]. In a 2020 rule for another source category involving chemical plants, EPA likewise provided two-year compliance periods for two facilities posing higher risks than Denka. 85 Fed. Reg. 49,084, 49,093 (2020); EPA Docket No. EPA-HQ-OAR-2018-0746-0189, Table 2a. The following chart includes the above-mentioned facilities and shows that EPA has provided two-year compliance periods to at least 18 facilities with cancer risks equal to or higher than Denka's alleged cancer risk over the past four years.



EPA's arbitrary and capricious treatment of Denka is also highlighted by an earlier residual risk rule for coke ovens, where EPA found that public health was protected with an ample margin of safety because *the rule reduced the cancer risk to* 2.7-in-10,000 and the cancer incidence to 0.06 per year. 70 Fed. Reg. 19,992, 19.993-94 (Apr. 15, 2005). This is the same annual cancer incidence (0.06) that EPA attributes to Denka's facility now—*before the required controls are installed*. 89 Fed. Reg. 42,963. Thus, EPA here claims that an annual cancer incidence rate of 0.06 for two years when caused by Denka would be an "imminent endangerment," even though EPA had previously determined that it would be perfectly acceptable for other facilities *indefinitely*.

To justify such disparate treatment of similarly situated parties, EPA must provide "a reasoned explanation and substantial evidence in the record." *Burlington N.*, 403 F.3d at 777. Here, the purported explanation is one sentence that refers to an unadjudicated and vigorously contested allegation in an EPA lawsuit that Denka's chloroprene emissions "pose an imminent and substantial endangerment under CAA §303, 42 U.S.C. §7603." Rule 42,955.

EPA's "finding" is belied by the record. There is no documentation in the record that EPA ever made such a finding or that it engaged in any process to reach this conclusion. As such, there is no "substantial evidence" to distinguish Denka from the many other facilities that EPA determined did *not* pose an imminent

endangerment despite posing higher risks than Denka. Moreover, *two months after* this purported finding, EPA issued the proposed rule that gave Denka (and all other facilities) two years to comply, thus recognizing (as EPA had in many prior rules) that an increase above 0.01% in the lifetime cancer risk to hypothetical person exposed continuously to a pollutant for 70 years does not represent an imminent endangerment. That leaves one likely reason for EPA to have reduced Denka's compliance period from two years to 90 days: to avoid summary judgement in the §303 lawsuit.

EPA's singling out of Denka with 90-day compliance deadline is therefore "arbitrary and capricious and cannot be upheld." *Burlington N.*, 403 F.3d at 777.

V. EPA's Effort To Withdraw Louisiana's Authority To Grant Extension Requests Is Unlawful.

Buried in a footnote, EPA mentions that it amended a regulation to state that "[a]pproval of an extension request under §63.6(i)(4)(ii)" *cannot* be delegated to a state agency. 89 Fed. Reg. at 42,955 (n.33) & 43,261 (modifying 40 C.F.R. §63.507(c)(6)). EPA provided no notice or explanation of this revision. Rather, this was a clear attempt to prevent Louisiana from granting a lawful compliance date extension to Denka. EPA's amendment is arbitrary and capricious and contrary to law.

A. EPA's Amendment Is Unlawful Because It Fails To Comply With The Statutory Process Required To Withdraw Delegated Authorities.

The Rule's amendment cannot preclude delegation of extension authority under §63.6(i)(4)(ii) because that provision has *already been delegated* to states in accordance with statutory requirements in §112(l) of the CAA and can be reversed only through a statutorily prescribed process for *withdrawing* delegation. The Rule's amendment is unlawful because EPA did not follow the required process.

Section 63.6(i)(4)(ii)—which authorizes the request of compliance extensions of §112(f) standards—is one of many "General Provisions" included in Part 63, Subpart A. EPA's regulations track which provisions have been delegated to each state and plainly show that Subpart A has been delegated to many states, including Louisiana and Texas. *See, e.g.*, 40 C.F.R. §§63.99(a)(19)(i), (44)(i) (tables showing delegation of Subpart A to Louisiana and Texas).

EPA delegated §63.6(i)(4)(ii) pursuant to the statutory framework in §112(l). 42 U.S.C. §7412(l). Section 112(l)(1) provides that any state may obtain EPA approval "for the implementation and enforcement ... of emission standards and other requirements for air pollutants" subject to §112. Because Louisiana has obtained such approval, EPA has delegated authority to Louisiana to grant compliance date extensions for rules issued under §112(f)—like the Rule at issue here.

Once authority is delegated to a state, §112(l)(6) sets forth a process that EPA must follow to withdraw such authority. Under §112(l)(6), EPA must (i) hold a public hearing; (ii) determine that the state is not appropriately administering its CAA program; (iii) provide notice to the state; (iv) provide an opportunity for corrective action; and (v) state the reasons for withdrawal in writing. 42 U.S.C. §7412(l)(6).

EPA's amendment of §63.507(c)(6) did not comply with *any* of the steps for withdrawal required by §112(l). It has held no public hearing, has provided no notice to any state, and has provided no opportunity for corrective action. EPA's amendment is therefore contrary to law and must be vacated.

B. EPA's Amendment Is Arbitrary And Capricious Because No Other Parallel Provision In Part 63 Commands That Extension Authority Under Section 63.6(i)(4)(ii) "Cannot Be Delegated."

Even if EPA's amendment of §63.507(c)(6) had followed the prescribed process for withdrawing delegated authority from a state, it is arbitrary and capricious because it is the only provision of its kind to say that approvals of §63.6(i)(4)(ii) requests "cannot be delegated" to state agencies.[9] 89 Fed. Reg. 43,261.

[9] Moreover, EPA's new version of §63.507(c)(6) does not even purport to prevent delegation of §63.6(i)(9), the provision that actually enables a state, as an Administrator with delegated authority, to grant an extension of compliance.

Section 63.507 is titled "Implementation and Enforcement" and was created in 2003 "to clarify which portions of the existing [§112 emission standards] contain authorities that can be delegated to State, local, and tribal agencies." 68 Fed. Reg. 37,334 (Aug. 22, 2003). When EPA promulgated §63.507, it was part of a global rulemaking that added parallel "Implementation and Enforcement" sections to 48 different subparts within 40 C.F.R. Part 63. *Id.* at 37,336. EPA made clear that "there are separate parts of each section 112 requirement that we cannot delegate to you." *Id.* The non-delegable authorities were not withheld as a matter of discretion but because the CAA or another statute prevents EPA from delegating them. As an example, EPA explained that "[b]ecause the Administrative Procedure Act requires us to … control requirements through Federal rulemaking, we cannot delegate our rulemaking authority to you." *Id.* at 37,334.

In the 2003 rulemaking, EPA clarified that four categories of provisions could not be delegated to states for Subpart U. *Id.* (promulgated provisions at 40 C.F.R. §§63.507(c)(1)-(4) listing approvals of alternatives to requirements, test methods, monitoring, and recordkeeping and reporting). These four categories were also adopted for every other "Implementation and enforcement" section across the other 47 subparts. 68 Fed. Reg. at 37,344-60. Importantly, EPA did *not* identify EPA's extension authority (40 C.F.R. §63.6(i) in Subpart A) as an authority that could not

be delegated. 68 Fed. Reg. at 37,349-50. Indeed, as discussed above, EPA *did* delegate its extension authority to multiple states.

Now, more than 20 years later, EPA has amended §63.507(c) to say that EPA's extension authority *cannot* be delegated, despite no relevant changes in the statutory requirements for delegation. Yet EPA has *not* revised the corresponding "Implementation and Enforcement" provisions in any of the other dozens of subparts to claim that extension authority "cannot" be delegated. For example, 40 C.F.R. Part 63, Subpart G—which EPA revised as part of the Rule here—includes an "Implementation and enforcement Section," but EPA did *not* amend those provisions to say that approval of §63.6(i)(4)(ii) requests could not be delegated. *See* 40 C.F.R. §63.153. "Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with *a reasoned explanation and substantial evidence* in the record, its action is arbitrary and capricious and cannot be upheld." *Burlington N.*, 403 F.3d at 777 (emphasis added).

Second, EPA's amendment is arbitrary and capricious because EPA failed to provide notice of or an explanation for its action. Because the proposed rule lacked any mention of an amendment to §63.507(c), impacted states had no reason to comment in defense of their extension authority—a quintessential "surprise switcheroo." *Env't Integrity Project*, 425 F.3d at 996. EPA compounded its error by

failing to provide any explanation for its amendment in the Final Rule. *Lilliputian*, 741 F.3d at 1313-14.

Third, EPA's amendment is arbitrary and capricious because it ignores fundamental principles of cooperative federalism and seeks to deprive states of their long-held authority under the CAA to be the primary regulators of facilities within their borders. "The Clean Air Act regulates air quality through a federal-state collaboration." *Ohio v. EPA*, 603 U.S. 279, 283 (2024) (quotation omitted). Further, the CAA assigns to the states the primary role in air pollution prevention and control as to existing sources. *Am. Elec. Power Co. v. Conn.*, 564 U.S. 410, 424–28 (2011); 42 U.S.C. §7401(a)(3). EPA's surprise amendment is inconsistent with these bedrock principles and, thus, arbitrary and capricious. *Texas v. EPA*, 829 F.3d 405, 428 (5th Cir. 2016) ("EPA's lack of deference to the state inverts the agency's 'ministerial function' in this system of 'cooperative federalism.'").

For these reasons, EPA's effort to prohibit Louisiana from granting such extensions "is arbitrary and capricious and cannot be upheld." *Burlington N.*, 403 F.3d at 777.

CONCLUSION

For the foregoing reasons, the challenged aspects of EPA's 2024 Rule should be vacated.

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITS

1. I certify that this brief complies with the type-volume limitation of FED. R. APP. P. 32(a)(7)(B) because it contains 8,669 words excluding the parts of the brief exempted by FED R. APP. P. 32(f) and Circuit Rule 32(e)(1).

2. I further certify that this brief complies with the typeface requirements of FED R. APP. P. 32(a)(5) and type-style requirements of FED R. APP. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point Times New Roman font.

Date: January 17, 2024

/s/ Jeffrey R. Holmstead
Jeffrey R. Holmstead

CERTIFICATE OF SERVICE

Pursuant to Rules 15(c)(2) and 25(d) of the Federal Rules of Appellate Procedure and Circuit Rule 15, I hereby certify that the foregoing OPENING BRIEF OF PETITIONERS DENKA PERFORMANCE ELASTOMER LLC, THE STATE OF LOUISIANA, AND THE LOUISIANA DEPARTMENT OF ENVIRONMENTAL QUALITY was electronically filed with the Clerk of the Court by using the appellate CM/ECF system, causing the above brief to be delivered electronically through CM/ECF on all ECF registered counsel of record.

Date: January 17, 2024

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